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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/822,716      | 03/30/2001  | David A. Edwards     | 2685.1003-008       | 7248             |

7590 08/23/2004

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209 MAIN STREET  
NO. CHELMSFORD, MA 01863

EXAMINER

HAGHIGHATIAN, MINA

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1616

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/822,716

**Applicant(s)**

EDWARDS ET AL.

**Examiner**

Mina Haghighatian

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10 and 13-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 13-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Receipt of amendments and response filed 05/24/04 is acknowledged. Claims 1-8, 10 and 13-52 are now pending.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8, 10, 13-17, 21-26, 28, 49 and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et al (6,043,214) in view of Maa et al (6,284,282 B1).

The references and the rejection are disclosed in the previous Office Action.

Claims 1-8, 10, 13-17, 21-28, 30-40, 44-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et al (6,043,214) in view of Weers et al (6,309,623 B1).

The references and the rejection are disclosed in the previous Office action.

Claims 18-20, 29 and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et al (6,043,214) in view of Weers et al (6,309,623 B1), as applied to claims 1-8, 10, 13-17, 21-28, 30-40 and 44-52 above, and further in view of International Ingredient Dictionary and Handbook.

Jensen et al and Weers et al, discussed above lack specific disclosure on addition of carboxylic acid. However Jensen teaches that hydrochloric acid is added to the formulations to adjust the pH. On the other hand, International ingredient Dictionary and Handbook discloses that carboxylic acids such as citric acids are well known pH adjusters in pharmaceutical and cosmetic formulations. Therefore, one of ordinary skill in the art would have been motivated to replace hydrochloric acid of Jensen with citric acid to perform a pH adjusting function. The expected result would be a successful formulation for the pulmonary delivery of insulin.

### ***Response to Arguments***

Applicant's arguments filed 05/24/04 have been fully considered but they are not persuasive.

Applicant argues that Jensen teaches a process of producing a dry powder formulation involving precipitation of an aqueous solution comprising insulin and an enhancer. Applicant continues by stating that Jensen's disclosure comparing process of precipitation to process of spray-drying, teaches away from the presently claimed invention. Applicant states that amending the instant claims to include additional features shows the importance of spray-drying process to control such features. However the arguments are not persuasive because the present claims are drawn to method of delivery a composition and the composition, and not a process of making the composition. All that is required to meet the limitations of claim 1 is a method of delivering to the pulmonary system a powder comprising a multivalent metal cation, an

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active agent and a carrier. Likewise all that is required to meet limitations of claim 30 is a composition comprising an active agent, a multivalent cation and a carrier. Jensen is clearly disclosing the composition and a method of delivering the said composition to the pulmonary system, successfully. The limitation of spray-drying has no patentable weight in a claim drawn to the method of delivery or the composition.

Applicant argues that Maa reference teaches particles with the desired aerodynamic diameter and geometric diameter and tap density of the particles prepared by freeze spray drying, thus one would not be motivated to combine Maa reference with Jensen's reference. This is not persuasive because it is shown that regardless of the process of making, Jensen teaches delivery of powders to the pulmonary system successfully. It is silent with regards to the particle properties. Maa reference is a supporting reference showing that the specific features of particles for pulmonary delivery are known in the art (It is noted that the properties of particles in claims drawn to method of delivery and compositions are not patentable limitations).

Applicant argues that Jensen and Weers references can not be combined because Jensen teaches away from Weers. Again the argument is regarding process of making the particles. As mentioned above, process of making is not a patentable features in claims drawn to method of delivery and compositions.

Applicant's arguments with regard to the combination of Jensen and International ingredient Dictionary and Handbook is moot in view of new grounds of rejection (as necessitated by amendments).

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

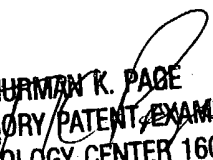
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghighatian  
August 20, 2004



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